K073701

Section 5 –510(k) Summary

Date Prepared: November 12, 2007

JAN 28 2008

Submitter: Dane Technologies, Inc.
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Trade Name of Device: Dane Technologies Wheelchair Mover

Classification: Wheelchair, Powered Wheelchair - 21 CFR 890.3860

Product Code: ITI

Predicate Device: Invacare, Model Storm TDX Power Wheelchair (K023589)

Device Description: The Wheelchair Mover is a motorized device that attaches to, and then pushes, various types of manual wheelchairs. The Wheelchair Mover is intended to push various types of manual wheelchairs up to 24 inches wide on dry, surfaced walkways indoors. Maximum patient plus wheelchair load capacity is 550 pounds.

The Wheelchair Mover helps caregivers move people seated in manual wheelchairs. It is particularly useful to help move heavy manual wheelchairs up ramps, but can be used in many circumstances to make it easier to move an occupied manual wheelchair.

A self-contained battery powers the Wheelchair Mover. It rolls on three wheels. The front, central one is the drive wheel that provides motive force. The Wheelchair Mover has attachment jaws that connect to the rear of the lower frame of manual wheelchairs. The person operating the Wheelchair Mover stands behind the Wheelchair Mover. The operator uses a steering handlebar and various hand-operated controls to direct the movement of the Wheelchair Mover and attached manual wheelchair with its occupant.

Intended Use: "The Wheelchair Mover is intended to push various types of manual wheelchairs up to 24 inches wide on dry, surfaced walkways indoors. Maximum patient plus wheelchair load capacity is 550 pounds."

This differs from the predicate primarily in that the predicate device is directed by the occupant; while the Wheelchair Mover is directed by a caregiver and must be attached to a manual wheelchair.

Functional and Safety Testing: The Dane Technologies WheelChair Mover has been tested to the relevant consensus standards for powered wheelchairs (21 CFR 890.3860, ProCode ITI) and has met the required performance criteria and functioned as intended.

Substantial Equivalence: In response to a request for a 513(g) determination, FDA sent a letter dated March 16, 2007 indicating that the Wheelchair Mover should be categorized as a "Wheelchair, Powered" [21 CFR 890.3860, ProCode ITI]. The Wheelchair Mover is substantially equivalent in that it is a self-contained, battery driven, device controlled by a user. It is different in that it is used to assist caregivers with the transport of patients in manual, non-powered wheelchairs from location to location. Steering, speed, and direction are under the control of the caregiver, not the patient. See details below.

Feature	Wheelchair Mover	Predicate Device
Wheel Configuration	3 wheels, with forward, central drive wheel	6 wheels (two being anti-tip), with two rear drive wheels
Operator	Trained operator	Chair occupant
Mechanism to attach to manual wheelchair	Hand-operated jaws and hitch plus foot pedals to move jaws either to left or right	Not available, not applicable
Steering mechanism	Steering bar	Hand operated joystick
Brake mechanism	Controller operated; regenerative braking	Controller operated; regenerative braking
Speed control	Thumb control levers	Hand operated joystick
Reverse throttle control	Yes	Hand operated joystick
Forward throttle control	Yes	Hand operated joystick
Hand-operated horn	Yes	No
Rabbit/turtle switch to set two ranges of speed	Variable speed, 2 range	Operator can set a maximum speed limit
Power source	Self-contained battery	Self-contained battery
Charge cord	Yes	Yes
Anti-static wire	Yes	Yes
Power control and emergency off	Yes	No
Control Status LED	Yes	Yes
Back-away button	Yes	No
Battery level Indicator	Yes	Yes
On/Off switch	Yes	Yes
Environment	Indoors	Outdoor/Indoor

Conclusion: The Wheelchair Mover is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 2008

Dane Technologies
c/o InterTek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road
Twinsburg, OH 44087

Re: K073701
Trade/Device Name: Dane Technologies Wheelchair Mover
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: January 11, 2008
Received: January 14, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

Device Name: Dane Technologies Wheelchair Mover

Indications for use:

The Wheelchair Mover is intended to push various types of manual wheelchairs up to 24 inches wide on dry, surfaced walkways indoors. Maximum patient plus wheelchair load capacity is 550 pounds.

Prescription Use (Part 21 CFR 801 Subpart D	AND/OR	Over-The-Counter Use **X** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhem

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073701